

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

ULLAH ET AL.

APPLICATION NO: UNKNOWN

FILED: HERewith

FOR: PHARMACEUTICAL COMPOSITION CONTAINING A
COMBINATION OF A STATIN AND ASPIRIN AND METHOD

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Before examining this application, please enter the following Preliminary Amendment which is being filed in conjunction with a Continuing application of U.S. Serial No. 09/040,794 filed March 18, 1998.

In the Specification:

Before the first line of the specification, please add the following sentence:

--This application is a divisional of application Serial No. 09/040,794, filed March 18, 1998.--

In the Claims:

Please cancel claims 1-26 and add the following claims 27-47 as follows:

27. A pharmaceutical composition comprising a statin cholesterol lowering agent and aspirin in a formulation to reduce statin:aspirin interaction.

28. The pharmaceutical composition as defined in Claim 27 wherein the statin and aspirin are formulated together in the same dosage formulation.

29. The pharmaceutical composition as defined in Claim 28 wherein the statin and aspirin are formulated together in a single tablet.

30. The pharmaceutical composition as defined in Claim 29 wherein the tablet includes a core and a coating layer surrounding said core and wherein one of the statin and aspirin is present in the core and the other is present in the coating layer surrounding the core.

31. The pharmaceutical composition as defined in Claim 30 wherein the aspirin is present in the core and the statin is present in the coating layer.

32. The pharmaceutical composition as defined in Claim 31 wherein the coating layer also includes one or more buffering agents.

33. The pharmaceutical composition as defined in Claim 27 wherein the statin is pravastatin, lovastatin, simvastatin, fluvastatin, atorvastatin or cerivastatin.

34. The pharmaceutical composition as defined in Claim 27 further including one or more buffering agents in combination with the statin.

35. The pharmaceutical composition as defined in Claim 29 further including an outer protective coating or finishing layer surrounding said tablet.

36. The pharmaceutical composition as defined in Claim 27 wherein the aspirin is in the form of enteric coated aspirin granules.

37. The pharmaceutical composition as defined in Claim 36 in the form of tablets or granules contained in a capsule.

38. The pharmaceutical composition as defined in Claim 36 wherein the enteric coated aspirin granules include a finishing overcoat, and the coated aspirin and the statin are in the form of a tablet or capsule.

39. The pharmaceutical composition as defined in Claim 38 wherein the coated aspirin granules and the statin in the form of granules are contained in the same capsule shells.

40. The pharmaceutical composition as defined in Claim 28 wherein the aspirin is in the form of enteric coated granules of aspirin and the statin is in the form of enteric coated granules of statin, in the form of compressed tablets or capsules.

41. The pharmaceutical composition as defined in Claim 27 in the form of a tablet or capsule containing both aspirin granules and statin granules.

42. The pharmaceutical composition as defined in Claim 41 wherein the statin is in the form of enteric coated statin granules.

43. The pharmaceutical composition as defined in Claim 41 wherein the statin granules include an outer protective coating to protect against interaction with aspirin.

44. The pharmaceutical composition as defined in Claim 27 further including an antioxidant.

45. The pharmaceutical composition as defined in Claim 44 wherein the antioxidant is vitamin C and/or vitamin E.

46. A method for lowering serum cholesterol or preventing or inhibiting or treating atherosclerosis or reducing risk of or treating a cardiovascular event or disease, coronary artery disease or cerebrovascular disease, which comprises administering to a patient in need of treatment a therapeutically effective amount of a pharmaceutical composition comprising a combination of a statin cholesterol lowering agent and aspirin in a single dosage form, which dosage form reduces interaction between the statin and aspirin.

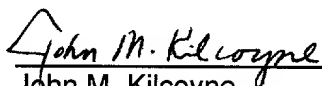
47. The method as defined in Claim 46 wherein the statin employed is pravastatin, lovastatin, simvastatin, atorvastatin, fluvastatin or cerivastatin.

REMARKS

This preliminary amendment is being filed to amend the claims to be directed to subject matter that was not allowed in the parent application. Claims 27-47 are pending in this application. Early examination is respectfully requested.

Respectfully submitted,

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000
(609) 252-5909



John M. Kilcoyne
Attorney for Applicants
Reg. No. 33,100

Date: April 2, 2001